UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, a corporation,	)	Docket No. 9297
and	)	
American Home Products Corporation, a corporation	)	

ANSWER OF RESPONDENT SCHERING-PLOUGH CORPORATION

Introduction

1. In late 1995, Schering-Plough Corporation ("Schering") brought a patent infringement suit against Upsher-Smith Laboratories, Inc. ("Upsher"), alleging infringement of a patent held by Schering covering a novel formulation for a sustained-release potassium chloride tablet. Schering's sustained-release potassium chloride tablet, made in conformity with the patented method, was sold under the brand name K-Dur®. In June 1997, Schering and Upsher settled the patent infringement lawsuit by dividing between them the remaining life of Schering's patent. Thus, although Schering's patent does not expire until September 2006, the settlement agreement grants a license to Upsher under Schering's patent to bring its product to market in September 2001, five years before patent expiration. Upsher gave Schering licenses to some products it had in development, for which Schering paid fair market value, including an up-front royalty payment of $28 million, followed by additional payments of $20 million and $12 million. Schering personnel, who were unaware of the patent litigation, had evaluated the

licenses and concluded that they were worth more to Schering than what Schering agreed to pay for them.

2. In late 1995, ESI Lederle ("ESI") filed an ANDA seeking approval to market its sustained-release potassium chloride product as bioequivalent to Schering's K-Dur®. Schering brought a patent infringement lawsuit against ESI in 1996, alleging that ESI's product infringed its patent. Considered objectively, ESI's defense to the case was very weak, and Schering was overwhelmingly likely to prevail in the litigation.

The court actively encouraged the parties to settle the case. The district court directed the magistrate judge to engineer a settlement. Schering advised the magistrate judge that it did not want to settle the case on any terms, and that it had concerns that a settlement pursuant to which Schering paid ESI a substantial sum of money and ESI stayed off the market might violate the antitrust laws. The magistrate judge assured Schering that his involvement obviated such concerns, and advised Schering to pay a small sum—$5 million, plus $10 million more if ESI obtained FDA approval by a certain date—in connection with a settlement in which ESI was permitted to bring its potassium chloride product to market over two years before Schering's patent expires.

3. The Complaint alleges that both of these settlement agreements restrain commerce unreasonably. It claims that consumers, as a result of these settlements, are being deprived of the benefit of generic competition, both from Upsher and ESI and also from other generic companies. Schering vigorously denies these allegations.

The Complaint ignores the fact that Schering has a valid patent, which gives it a legal right to exclude from the market products that infringe it. The Complaint does not allege that Schering's patent is invalid, or that it would not be infringed by Upsher's and ESI's products. And the Complaint fails to allege that the settlements do not reflect the parties' positions in the respective litigations. Each settlement agreement is as good or better for consumers than the likely outcome of continued litigation.

Pursuant to Rule 3.12 of the Commission's Rules of Practice, 16 C.F.R. § 3.12, respondent Schering-Plough Corporation ("Schering") hereby answers the complaint in the above-captioned matter.

Except to the extent specifically admitted herein, Schering denies each and every allegation contained in plaintiff's complaint.

1. This action challenges unlawful agreements by Schering, Upsher-Smith, and AHP to delay the entry of low-cost generic competition to Schering's highly profitable prescription drug K-Dur 20, a product used to treat patients who suffer from insufficient levels of potassium, a condition that can lead to serious cardiac problems.

   Answer:

   Schering admits that the prescription drug K-Dur 20 is used to treat patients who suffer from insufficient levels of potassium, a condition that can lead to serious cardiac problems, and that this action purports to challenge two separate agreements, one between Schering and Upsher-Smith, and one between Schering and AHP, and denies the remaining allegations in paragraph 1 of the complaint. In particular, each agreement actually accelerated the entry of competition to K-Dur.

2. When confronted with the prospect of competition to K-Dur 20 through generic entry by Upsher-Smith and ESI Lederle, Incorporated ("ESI"), a division of AHP, Schering structured and entered into agreements with Upsher-Smith, AHP, and ESI that are keeping Upsher-Smith, ESI, and all other potential generic competitors out of the market. These agreements have cost consumers in excess of $100 million.

   Answer:

   Schering denies the allegations in paragraph 2 of the complaint. Paragraph 2 omits to state that Schering has a patent, that it sued separately Upsher and ESI for infringement, that the agreements settled the infringement suits, and permitted allegedly infringing products to enter the market before patent expiration.

3. Respondent Schering is a New Jersey corporation with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey. Schering is engaged in the discovery, development, and marketing of brand-name and generic drugs, as well as over-the-counter healthcare and animal care products. Schering's net sales for 1999 were approximately $9.2 billion.

Answer:

Schering admits the allegations in paragraph 3 of the complaint.

4. Respondent Upsher-Smith is a Minnesota corporation with its principal place of business at 14905 23rd Avenue North, Plymouth, Minnesota. Upsher-Smith is engaged in the discovery, development, and marketing of drugs. Upsher-Smith markets twelve brand-name products, all of which are sold in the United States.

Answer:

Schering is without sufficient knowledge or information to admit or deny the allegations in paragraph 4 of the complaint.

5. Respondent AHP is a Delaware corporation with its principal place of business at 5 Giralda Farms, Madison, New Jersey. AHP engages in the discovery, development, and marketing of brand-name and generic drugs, as well as over-the-counter medications. AHP had net sales of $13.5 billion in 1999.

Answer:

Schering is without sufficient knowledge or information to admit or deny the allegations in paragraph 5 of the complaint.

6. ESI Lederle, Incorporated, a division of AHP, engages in the research, manufacture, and sale primarily of generic drugs.

Answer:

Schering is without sufficient knowledge and information to admit or deny the allegations in paragraph 6 of the complaint.

7. Schering, Upsher-Smith, and AHP, at all relevant times herein, have been, and are now, corporations as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

Answer:

Schering admits the allegations in paragraph 7 of the complaint.

8. Respondents' acts and practices, including the acts and practices alleged herein, are in or affect commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

Answer:

Schering admits the allegations in paragraph 8 of the complaint.

9. Under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., approval by the Food and Drug Administration ("FDA") is required before a company may market or sell a prescription drug in the United States.

Answer:

Schering admits that under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., approval by the Food and Drug Administration ("FDA") is required before a company may market or sell a new prescription drug in the United States.

10. Newly developed prescription drugs are often protected by patents and marketed under proprietary brand names. Such new drugs are referred to as "brand name drugs" or "branded drugs." FDA approval for a branded drug is generally sought by filing a New Drug Application ("NDA") with the FDA.

Answer:

Schering admits that newly developed prescription drugs are often protected by patents and marketed under proprietary brand names, that such new drugs are sometimes referred to as "brand name drugs" or "branded drugs," and that FDA approval for a branded prescription drug is generally sought by filing a New Drug Application ("NDA") with the FDA.

11. Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 (the "Hatch-Waxman Act"), to facilitate entry of generic drugs while maintaining incentives for new drug development.

Answer:

Schering admits that Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. §§ 156, 271, 355 (the "Hatch-Waxman Act"), that one purpose of the Hatch-Waxman Act is to facilitate entry of generic drugs while maintaining incentives for new drug development, and that the Hatch-Waxman Act was also intended to extend patent terms in certain circumstances.

12. FDA approval for a generic drug is generally sought by filing an Abbreviated New Drug Application ("ANDA") with the FDA. The ANDA applicant has to demonstrate that the generic drug is bioequivalent to the brand name drug that it references.

Answer:

Schering admits that FDA approval for a generic prescription drug is generally sought by filing an Abbreviated New Drug Application ("ANDA") with the FDA, and that the ANDA applicant has to demonstrate, among other things, that the generic drug is bioequivalent to the brand name drug that it references.

13. When a brand name drug is protected by one or more patents, an ANDA applicant that intends to market its generic product prior to expiration of any patents may proceed to seek FDA approval, but must certify in the ANDA either that (1) the generic version does not infringe the patents on the brand name drug or (2) the patents are invalid. This is called a "Paragraph IV Certification."

Answer:

Schering admits that when a brand name prescription drug is protected by one or more patents, an ANDA applicant that intends to market its generic prescription product prior to expiration of any patents listed in the "Orange Book" may proceed to seek FDA approval, but must certify in the ANDA either that (1) the generic version does not infringe the patents on the brand name drug or (2) the patents are invalid, and that this is called a "Paragraph IV Certification."

14. The ANDA applicant must then notify the NDA holder and the patent holder of the filing of its ANDA. If, within 45 days of receiving such notification, a patent infringement suit is initiated against the ANDA applicant, the FDA must stay its final approval of the ANDA for the generic drug until the earliest of (1) the patent expiration, (2) a judicial determination of the patent litigation, or (3) the expiration of a 30-month waiting period.

Answer:

Schering admits that after filifn an ANDA with a paragraph IV certification, the ANDA applicant must then notify the NDA holder and the patent holder of the filing of its ANDA, and that if, within 45 days of receiving such notification, a patent infringement suit is initiated against the ANDA applicant, the FDA must stay its final approval of the ANDA for the generic drug until the earliest of (1) the patent expiration, (2) a judicial determination of the patent litigation, or (3) the expiration of a 30-month waiting period which may be extended or shortened by the court.

15. The Hatch-Waxman Act gives the first firm filing an ANDA for a generic version of a brand name drug with a Paragraph IV Certification a period of protection from competition from other generic versions of the drug. The FDA may not approve other generic versions of the same drug until 180 days after the earlier of the date on which (1) the first firm begins commercial marketing of its generic version of the drug, or (2) a court finds the patents claiming the brand name drug are invalid or not infringed. This is referred to as "the 180-day Exclusivity Period."

Answer:

Schering admits that if a firm has filed an ANDA for a generic version of a brand name drug with a Paragraph IV Certification, the Hatch-Waxman Act provides that the FDA may not make effective a subsequent ANDA until 180 days after the earlier of the date on which (1) the first firm begins commercial marketing of its ANDA product, or (2) a court finds the patents claiming the brand name drug to be invalid or not infringed, and that this sometimes is referred to as "the 180-day Exclusivity Period."

16. If the first firm filing an ANDA loses its patent litigation with the patent holder, no firm is given a 180-day Exclusivity Period.

Answer:

Schering states that to the extent the allegations in paragraph 16 of the complaint amount to conclusions of law, no response thereto is required, and denies any remaining allegations of paragraph 16 of the complaint.

17. Generic entry generally leads to a significant erosion of the branded drug's market share and unit and dollar sales within the first year. As additional generic drugs enter, the price of the generic drugs typically decreases even further and the branded drug's market share erodes further.

Answer:

Schering admits that generic entry generally leads to erosion of the branded drug's market share and unit and dollar sales within the first year, and that as some additional generic drugs enter, the price of the generic drugs may decrease even further.

18. Pharmacists generally are permitted, and in some instances required, to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that the branded product be dispensed.

Answer:

Schering admits the allegations in paragraph 18 of the complaint.

19. Certain third-party payers of prescription drugs (e.g., managed care plans, Medicaid programs) encourage or insist on the use of generic drugs in lieu of their branded counterparts wherever possible.

Answer:

Schering admits that certain third-party payers of prescription drugs (e.g., managed care plans, Medicaid programs) encourage on the use of generic drugs in lieu of their branded counterparts, and otherwise denies the allegations.

20. The relevant geographic market in which to evaluate the conduct of Schering, Upsher-Smith, and AHP is the United States.

Answer:

Schering states that to the extent the allegations in paragraph 20 of the complaint amount to conclusions of law, no response thereto is required, and denies any remaining allegations in paragraph 20 of the complaint.

21. The relevant product markets are the manufacture and sale of all potassium chloride supplements approved by the FDA, and narrower markets contained therein, including the manufacture and sale of 20 milliequivalent extended-release potassium chloride tablets and capsules.

Answer:

Schering states that to the extent the allegations in paragraph 21 of the complaint amount to conclusions of law, no response thereto is required, and denies any remaining allegations in paragraph 21 of the complaint.

22. Potassium chloride supplements are used to treat patients with depleted potassium levels, a condition that typically occurs when people take certain anti-hypertensive medications to lower blood pressure. Depleted potassium levels can cause dangerous cardiac problems.

Answer:

Schering admits that potassium supplements are used to treat patients with depleted potassium levels, that depleted potassium levels sometimes occur when people take certain medications, and that depleted potassium levels can cause dangerous cardiac problems, and denies the remaining allegations in paragraph 22 of the complaint.

23. Patients who suffer from depleted potassium levels have no practical substitute for potassium chloride supplements.

Answer:

Schering denies the allegations in paragraph 23 of the complaint.

24. For clinical reasons, among others, physicians and patients prefer 20 milliequivalent extended-release potassium chloride tablets over other forms and dosages of potassium chloride.

Answer:

Schering is without sufficient knowledge or information regarding the minds of physicians and patients to admit or deny the allegations in paragraph 24 of the complaint.

25. The existence of other potassium chloride products has not significantly constrained Schering's pricing of K-Dur 20.

Answer:

Schering denies the allegations in paragraph 25 of the complaint.

26. Schering has approximately 69% of the sales of potassium chloride supplements.

Answer:

Schering denies the allegations in paragraph 26 of the complaint.

27. Schering's K-Dur 20 has 100% of the sales of 20 milliequivalent extended-release potassium chloride tablets and capsules.

Answer:

Schering admits that K-Dur 20 has 100% of the sales of 20 milliequivalent extended-release potassium chloride tablets, although there are other non-extended release 20 milliequivalent potassium supplement products on the market.

28. At all times relevant herein, entry into the relevant markets was restricted and unlikely to diminish Schering's market share. Before entry could occur, potential entrants were required to, *inter alia,* file an NDA or an ANDA with the FDA, and obtain FDA final approval. At all relevant times, only one NDA for a new potassium chloride supplement was pending before the FDA. That NDA, for a powder form, has not been approved; and, even if it were approved, because of the disadvantages of potassium chloride powders compared to tablets, a new potassium chloride powder would be unlikely to diminish Schering's market share. If a new NDA were to be filed with the FDA, final approval would likely take a minimum of 12-18 months.

Answer:

Schering denies the allegations in paragraph 28 of the complaint except states that to the

extent those allegations amount to conclusions of law, no response thereto is required.

29. At all times relevant herein, FDA final approval of an ANDA for a generic version of K-Dur 20 for anyone other than Upsher-Smith was blocked. Pursuant to the Hatch-Waxman Act, Upsher-Smith was eligible for the right to a 180-day Exclusivity Period for the sale of a generic version of K-Dur 20. As a result, no company could obtain final FDA approval of an ANDA to market or sell a generic version of K-Dur 20 until 180 days after Upsher-Smith first sold its product, or until Upsher-Smith's exclusivity right is relinquished, forfeited or otherwise expired.

Answer:

Schering denies the allegations in paragraph 29 of the complaint. When Schering entered into its settlement agreement with Upsher-Smith, the FDA regulation provided that Upsher must "successfully defend" against Schering's infringement suit to obtain exclusivity. The settlement was not a "successful defense."

30. At all times relevant herein, the existence of generic versions of branded potassium chloride supplements other than K-Dur 20 has not constrained Schering's market power in the potassium chloride supplement market.

Answer:

Schering admits that currently there are no generic versions of K-Dur 20 on the market, and denies the allegations in paragraph 30 of the complaint.

31. Schering manufactures and markets two extended-release microencapsulated potassium chloride products: K-Dur 20 milliequivalent ("K-Dur 20") and K-Dur 10 milliequivalent ("K-Dur 10"). Both products are marketed as brand name drugs.

Answer:

Schering admits the allegations in paragraph 31 of the complaint.

32. In 1998, sales of Schering's two K-Dur products were over $220 million.

Answer:

Schering admits that combined dollar sales in 1998 of K-Dur 10 and K-Dur 20 were over $220 million.

33. Potassium chloride, the active ingredient in potassium chloride supplements, is not patentable.

Answer:

Schering admits that potassium chloride, the active ingredient in potassium chloride supplements, is not patented.

34. Schering's K-Dur 20 and K-Dur 10 are covered by a formulation patent owned by Schering, patent number 4,863,743 (the "743 patent"), which claims a controlled release potassium chloride tablet. The 743 patent expires on September 5, 2006.

Answer:

Schering admits that K-Dur 20 and K-Dur 10 are covered by a patent owned by Key Pharmaceuticals, Inc., a division of Schering, patent number 4,863,743, which claims a controlled-release dispersible potassium chloride tablet, that the '743 patent expires on September 5, 2006, and denies the remaining allegations in paragraph 34 of the complaint.

35. The allegedly novel aspect of the 743 patent is the composition of the coating material applied to previously known potassium chloride crystals.

Answer:

Schering admits that the '743 patent claims a novel composition for coating potassium chloride crystals and denies the remaining allegations in paragraph 35 of the complaint.

36. Schering anticipated generic entry prior to expiration of its 743 patent.

Answer:

Schering denies the allegations in paragraph 36 of the complaint.

37. Prior to 1997, Schering projected that the first year of low-priced generic competition would reduce branded K-Dur 20's sales by over $30 million.

Answer:

Schering denies the allegations in paragraph 37 of the complaint.

38. On August 6, 1995, Upsher-Smith filed an ANDA with the FDA to market Klor Con M20, a generic version of Schering's K-Dur 20. Upsher-Smith's ANDA was the first for a generic version of K-Dur 20. Upsher-Smith submitted a Paragraph IV Certification with this ANDA and, on November 3, 1995, Upsher-Smith notified Schering of its Paragraph IV Certification and ANDA filing.

Answer:

Schering admits that in August 1995, Upsher-Smith filed with the FDA an ANDA referencing K-Dur 20 for a proposed product to be called Klor Con M20, that to Schering's knowledge Upsher-Smith's ANDA was the first ANDA filed with the FDA referencing K-Dur 20, that Upsher-Smith submitted a Paragraph IV certification with its ANDA, and that Upsher-Smith notified Schering of its Paragraph IV certification on November 3, 1995.

39. Schering sued Upsher-Smith for patent infringement in the United States District Court for the District of New Jersey on December 15, 1995, alleging that Upsher-Smith's Klor-Con M20 infringed Schering's 743 patent. This lawsuit triggered the statutory waiting period of up to 30 months for final FDA approval of the Upsher-Smith product.

Answer:

Schering admits that it sued Upsher-Smith for patent infringement in the United States District Court for the District of New Jersey on December 15, 1995, alleging that Upsher-Smith's proposed potassium chloride product infringed Schering's '743 patent, and that the filing of this lawsuit triggered the statutory waiting period of 30 months (unless extended or shortened by the court) for final FDA approval of the Upsher-Smith product.

40. This lawsuit was strongly contested by Upsher-Smith.

Answer:

Schering admits that the lawsuit was contested by Upsher-Smith.

41. As the first ANDA filer with a Paragraph IV Certification for a generic version of Schering's K-Dur 20, Upsher-Smith is eligible for the 180-day Exclusivity Period.

Answer:

Schering denies the allegations in paragraph 41 of the complaint. At the time Schering settled with Upsher, FDA regulations provided that Upsher must "successfully defend"

Schering's lawsuit to obtain exclusivity. By settling, Upsher did not "successfully defend" the lawsuit, however. Over a year after the settlement, the FDA changed its regulation to remove the successful defense requirement. The FDA is currently considering exclusivity on a case-by-case basis, and has proposed a new regulation concerning exclusivity. It is unclear whether Upsher is eligible for exclusivity under the FDA's current interpretation of the Hatch-Waxman Act, and its regulations thereunder.

42. Because Upsher-Smith is eligible for the 180-day Exclusivity Period, no other generic manufacturer can obtain final FDA approval to market a generic version of K-Dur 20 until after the exclusivity period has expired, whether or not the other marketer has a product that infringes the Schering patent.

Answer:

Schering denies the allegations in paragraph 42 of the complaint, and hereby incorporates by reference its answer to paragraph 41 of the complaint. In addition, Schering's settlement with Upsher contains no provision that would prevent Upsher from waiving, transferring or otherwise relinquishing any right to exclusivity.

43. During the first half of 1997, Upsher-Smith prepared to launch commercially Klor Con M20 no later than May 1998, the month in which the 30-month stay of FDA approval was to expire.

Answer:

Schering is without sufficient knowledge or information to admit or deny the allegations in paragraph 43 of the complaint, and therefore denies them.

44. On June 17, 1997, on the eve of their patent trial, Schering and Upsher-Smith agreed to settle their litigation. Under the settlement, Schering agreed to make unconditional payments of $60 million to Upsher-Smith; Upsher-Smith agreed not to enter the market, either with the allegedly infringing generic version of K-Dur 20 or with any other version of K-Dur 20, regardless of whether such product would infringe Schering's patents, until September 2001; both parties agreed to stipulate to the dismissal of the litigation without prejudice; and Schering received licenses to market five Upsher-Smith products.

Answer:

Schering admits that Schering and Upsher-Smith settled Schering's patent infringement lawsuit on or about June 17, 1997, prior to their patent litigation trial; that as part of the

settlement the parties agreed to a dismissal of the litigation without prejudice; that as part of the settlement Schering agreed to grant Upsher-Smith a license under Schering's '743 patent allowing Upsher's Klor-Con M20 product on the market in September 2001, five years before expiration of Schering's patent; and that Schering received licenses to market six Upsher-Smith products in exchange for license fees of $60 million, plus additional fees to be paid upon completion of certain milestones, and denies the remaining allegations of paragraph 44 of the complaint. Schering categorically denies that it agreed to make any "unconditional" payments of $60 million. Schering's payments to Upsher were conditioned on receipt of licenses to market Upsher's Niacor-SR and other products on a worldwide basis (excluding the United States, Canada and Mexico).

45. The $60 million payment from Schering to Upsher-Smith was unrelated to the value of the products Upsher-Smith licensed to Schering.

Answer:

Schering denies the allegations in paragraph 45 of the complaint. Schering's valuation of the licenses at over $60 million is supported by a contemporaneous evaluation by two Schering employees who had no knowledge of the patent litigation.

46. The licensed products were of little value to Schering. Schering never sold four of the five licensed products, made minimal sales of the fifth, and has no expectation of making additional sales of any of the five products.

Answer:

Schering denies the allegations in paragraph 46 of the complaint.

47. A court decision in the Schering patent infringement suit against Upsher-Smith would have removed barriers to generic competition, regardless of which party prevailed in the suit. If Upsher-Smith had prevailed, the FDA would have been permitted to grant final approval to Upsher-Smith's generic version of K-Dur 20, allowing Upsher-Smith to offer generic competition to Schering. After Upsher-Smith's 180-day Exclusivity Period had run, other potential generic competitors would have been eligible for final FDA approval. If Schering had prevailed, Upsher-Smith would not have been eligible for the 180-day Exclusivity Period. Since no other firm would have been eligible for the 180-day Exclusivity Period, there would have been no 180-day Exclusivity Period blocking final

FDA approval of other generic competitors. Thus, the settlement agreement between Schering and Upsher-Smith preserved a barrier to generic competition to K-Dur 20.

Answer:

Schering denies the allegations in paragraph 47 of the complaint, and hereby incorporates by reference its answers to paragraph 29, 41 and 42 of the complaint.

48. In November 1998, Upsher-Smith received final FDA approval to market its Klor Con M20 generic version of Schering's K-Dur 20.

Answer:

Schering admits that in November 1998, Upsher-Smith received FDA approval to market its proposed potassium chloride product.

49. Pursuant to its agreement with Schering, Upsher-Smith has not marketed Klor Con M20, nor has it attempted to develop another generic version of Schering's K-Dur 20.

Answer:

Schering admits that Upsher-Smith has not marketed Klor Con M20, is without sufficient information or knowledge to admit or deny the allegation that Upsher has not attempted to develop another generic version of Schering's K-Dur 20, and denies the remaining allegations in paragraph 45 of the complaint. Absent the settlement between Schering and Upsher, Schering's patent would have presented a legal barrier to Upsher's marketing of Klor-Con M20.

50. Under the Hatch-Waxman Act, the FDA is not permitted to grant final approval to a generic version of K-Dur 20, other than Upsher-Smith's Klor Con M20, until the 180-day Exclusivity Period has run.

Answer:

At the time Schering settled with Upsher, FDA regulations required Upsher to "successfully defend" Schering's lawsuit to obtain exclusivity. By settling, Upsher did not "successfully defend" the lawsuit. Over a year after the settlement, the FDA changed its regulation to remove the successful defense requirement. The FDA is currently considering exclusivity on a case-by-case basis, and has proposed a new regulation

concerning exclusivity. It is unclear if Upsher is eligible for exclusivity under the FDA's current interpretation of the Hatch-Waxman Act, and its regulations thereunder. Schering therefore denies the allegations in paragraph 50 of the complaint, except states that to the extent those allegations amount to conclusions of law, no response thereto is required.

51. On December 29, 1995, ESI submitted an ANDA to the FDA to market a generic version of Schering's K-Dur 20. ESI submitted a Paragraph IV Certification with this filing and notified Schering of its Paragraph IV Certification and ANDA filing.

Answer:

Schering admits that on December 22, 1995, ESI submitted to the FDA an ANDA referencing K-Dur 20 for a proposed product, and that on December 29, 1995 ESI notified Schering of its Paragraph IV certification.

52. ESI planned to launch its generic version of K-Dur 20 after Upsher-Smith's 180-day Exclusivity Period expired.

Answer:

Schering is without sufficient knowledge or information to admit or deny the allegations in paragraph 52 of the complaint, and therefore denies them.

53. Schering sued ESI for patent infringement in the United States District Court for the Eastern District of Pennsylvania on February 16, 1996, alleging that ESI's generic version of Schering's K-Dur 20 infringed Schering's 743 patent. Schering's lawsuit triggered the statutory waiting period of up to 30 months for FDA approval of the ESI product.

Answer:

Schering admits that it sued ESI for patent infringement in the United States District Court for the Eastern District of Pennsylvania on February 16, 1996, alleging that ESI's proposed product infringes Schering's '743 patent, and that the filing of Schering's lawsuit triggered the statutory waiting period of 30 months (unless extended or shortened by the court) for FDA approval of the ESI product.

54. By the end of January 1998, Schering, AHP, and ESI had reached an agreement in principle to settle their patent litigation.

Answer:

Schering admits that in January 1998, Schering and ESI had reached an agreement in principle to settle their patent litigation, and denies the remaining allegations in paragraph 59 of the complaint.

55. Pursuant to their agreement in principle, Schering agreed to pay ESI up to $30 million; AHP and ESI agreed to refrain from marketing the allegedly infringing generic version of K-Dur 20 or with any other generic version of K-Dur 20, regardless of whether such product would infringe Schering's patents, until January 2004; AHP and ESI agreed to refrain from marketing more than one generic version of K-Dur 20 between January 2004 and September 2006; and AHP and ESI agreed not to conduct, sponsor, file or support a study of the bioequivalence of any product to K-Dur 20 prior to September 2006, when the K-Dur 20 patent will expire. Schering agreed to pay ESI $5 million up front; an additional $10 million if ESI could demonstrate that its generic version of K-Dur 20 was able to be approved by the FDA under an ANDA on or before June 30, 1999; and another $15 million for licenses of two generic products that ESI was developing. The payments for the licenses included $5 million to be paid within ten days of execution of the agreement, plus $10 million to be paid in annual installments over seven years.

Answer:

Schering admits that, as a part of the settlement agreement, Schering granted ESI a license under Schering's '743 patent allowing ESI's proposed product on the market in January 2004, over two years before the expiration of Schering's patent, that Schering agreed to pay ESI $5 million with a possible additional payment if ESI attained FDA approval for its proposed product by a specified date, that Schering obtained licenses to two products in exchange for licensing fees of $5 million plus additional fees of $10 million to be paid in annual installments over seven years, and that the settlement agreement states that "AHP and ESI shall not . . . prior to September 5, 2006, (i) apply for or sponsor or support an application for AB rating . . . for any potassium chloride product with respect to K-Dur® 10 or K-Dur® 20; (ii) conduct sponsor, file or support a substitutability study for a potassium chloride product with respect to K-Dur® 10 or K-Dur® 20; or (iii) conduct, sponsor, file or support a study of the bioequivalence or

therapeutic equivalence of a potassium chloride product to K-Dur® 10 or K-Dur® 20." Schering denies that this language was intended, or has had the effect, of preventing AHP or ESI from marketing non-infringing products, and in fact, at the time of the agreement and currently, AHP markets potassium chloride products that do not infringe the '743 patent. Schering's intent was to prevent ESI from making insignificant changes to its proposed ANDA product, and refiling its ANDA with another infringing product.

56. Schering has made no sales to date of the two products it licensed from ESI.

Answer:

Schering admits that it has made no sales to date of the two products it licensed from ESI, but is actively working to obtain regulatory approvals for those products and expects to market both products in the relatively near future.

57. Instead of being based on the value of the licensed products, the $15 million license payment is based on the amount that ESI wanted in order to settle its patent litigation with Schering.

Answer:

Schering denies the allegations in paragraph 57 of the complaint.

58. On June 19, 1998, Schering and ESI executed their final settlement agreement. Their patent litigation had previously been dismissed with prejudice.

Answer:

Schering admits that on June 19, 1998, Schering and ESI executed a final settlement agreement and that the court had previously dismissed the litigation with prejudice, with the right to re-open if the parties did not sign a final settlement agreement, and denies the remaining allegations in paragraph 58 of the complaint.

59. Schering has paid ESI over $20 million and continues to make annual payments to ESI under the terms of their agreement.

Answer:

Schering admits that it paid ESI $5 million ten days after executing and delivering the final settlement agreement, that it paid ESI $10 million ten days after ESI provided Schering with a copy of the FDA's approval letter for ESI's proposed product, that it paid ESI a $5 million license fee for the licenses to two ESI products, and that it has made and continues to make license fee payments to ESI.

60. ESI received tentative approval of its ANDA from the FDA on May 11, 1999, but is not eligible for final approval until Upsher-Smith's 180-day Exclusivity Period expires.

Answer:

Schering admits that ESI received approval of its ANDA from the FDA on May 11, 1999, and denies the remaining allegations in paragraph 60 of the complaint, except states that to the extent those allegations amount to conclusions of law, no response thereto is required.

61. Andrx Corporation ("Andrx") filed an ANDA for a generic version of Schering's K-Dur 20 on June 2, 1999. Schering has not sued Andrx for infringement of the '743 patent.

Answer:

Schering admits that Andrx corporation filed an ANDA referencing Schering's K-Dur 20 on June 2, 1999, that Schering has not sued Andrx for infringement of the '743 patent, and denies the remaining allegations in paragraph 61 of the complaint.

62. Andrx cannot market its product until Upsher-Smith's 180-day Exclusivity Period has run.

Answer:

Schering denies the allegations in paragraph 62 of the complaint. Andrx cannot market its product because it has not received tentative approval from the FDA.

63. The acts and practices of the respondents as herein alleged have had the purpose and effect to restrain competition unreasonably and to injure competition by preventing or discouraging the entry of generic K-Dur 20 products into the relevant markets.

Answer:

Schering denies the allegations in paragraph 63 of the complaint.

64. By making cash payments to Upsher-Smith and ESI, Schering induced them to agree to delay launching generic versions of K-Dur 20. Absent those payments, neither Upsher-Smith nor ESI would have agreed to delay its entry for so long.

Answer:

Schering denies the allegations in paragraph 64 of the complaint.

65. By making cash payments to Upsher-Smith and ESI, Schering protected itself from competition in the relevant markets from Upsher-Smith and ESI until 2001 and 2004, respectively.

Answer:

Schering denies the allegations in paragraph 65 of the complaint.

66. Upsher-Smith's agreement with Schering not to compete with a generic version of K-Dur 20 until September 2001 has the effect of delaying entry into the relevant market by any other potential generic competitor. As the first ANDA filer for a generic version of K-Dur 20, Upsher-Smith is entitled to 180 days of market exclusivity before any other generic competitor may enter with its own generic version of K-Dur 20. By avoiding a court decision that would have either (a) triggered this 180-day Exclusivity Period (in the event Upsher-Smith prevailed) or (b) resulted in its forfeiture (in the event Schering prevailed), the challenged agreement delays the start of Upsher-Smith's 180-day Exclusivity Period until September 2001 and, as a result, the entry of competition from other generic manufacturers until March 2002.

Answer:

Schering denies the allegations in paragraph 66 of the complaint, and hereby incorporates by reference its answers to paragraphs 29, 41 and 42 of the complaint.

67. As a result of respondents' conduct as herein alleged, consumers are being deprived of the benefits of competition from Upsher-Smith, ESI, or other generic competitors. Without this lower-priced generic competition, consumers, pharmacies, hospitals, insurers, wholesalers, government agencies, managed care organizations, and others are forced to purchase Schering's more expensive K-Dur 20 product.

Answer:

Schering denies the allegations in paragraph 67 of the complaint. Indeed, as a result of the settlement, Upsher's Klor Con M20 can enter the market in less than five months, more than five years before the expiration of Schering's patent. ESI's generic product can enter the market over two and a half years before Schering's patent expires. No other generic versions of K-Dur 20 have been approved by the FDA.

68. The agreement between Schering and Upsher-Smith that Upsher-Smith will not compete by marketing any generic version of Schering's K-Dur 20 until September 2001 unreasonably restrains commerce, and is therefore an unfair method of competition, in violation of Section 5 of the FTC Act.

Answer:

Schering denies the allegations in paragraph 68 of the complaint. The agreement between Schering and Upsher-Smith is reasonable because it allows Upsher's proposed product on the market long before expiration of Schering's patent. The settlement is also reasonable because under the agreement, Schering agreed to compromise its right to exclude by splitting the remaining life of its patent according to the objective merits of the patent litigation between Schering and Upsher. Accordingly, the procompetitive benefits of the settlement outweigh any actual or potential anticompetitive effects

69. The agreement between Schering, AHP, and ESI that ESI will not compete by marketing any generic version of Schering's K-Dur 20 until January 2004, market more than one generic version of Schering's K-Dur 20 between January 2004 and September 2006, or support any study of the bioequivalence or therapeutic equivalence of a product to K-Dur 20 until September 5, 2006, unreasonably restrains commerce, and is therefore an unfair method of competition, in violation of Section 5 of the FTC Act.

Answer:

Schering denies the allegations in paragraph 69 of the complaint.

70. Schering has monopoly power in the manufacture and sale of potassium chloride supplements approved by the FDA and narrower markets contained therein, and engaged in conduct intended to unlawfully preserve such monopoly power in violation of Section 5 of the FTC Act.

Answer:

Schering denies the allegations in paragraph 70 of the complaint.

71. Schering conspired separately with Upsher-Smith and AHP that Schering monopolize the manufacture and sale of potassium chloride supplements approved by the FDA and narrower markets contained therein, and all three respondents acted with specific intent and engaged in overt acts in furtherance of these conspiracies to monopolize the relevant markets, in violation of Section 5 of the FTC Act.

Answer:

Schering admits that it entered into wholly separate settlement agreements with Upsher, on the one hand, and with ESI on the other. Schering denies the remaining allegations in paragraph 71 of the complaint.

AFFIRMATIVE DEFENSES

Schering states the following affirmative defenses without assuming the burden of proof on any such defenses that would otherwise fall on plaintiff.

FIRST AFFIRMATIVE DEFENSE

The complaint fails to state, in whole or in part, a claim upon which relief can be granted for various reasons, including, but not limited to, the fact that the complaint fails to acknowledge that Schering has a valid patent giving it a right to exclude any infringing products, and the fact that Schering settled its separate lawsuits with Upsher and ESI by compromising Schering's patent rights in a manner that reflects the objective merits of the underlying patent cases.

SECOND AFFIRMATIVE DEFENSE

The complaint fails to state, in whole or in part, a claim upon which relief can be granted because any alleged exclusionary effect on third parties is the direct result of action by the

federal government, not Schering's settlements with Upsher. Accordingly, under the *Noerr-Pennington* doctrine, Schering cannot be liable for any such alleged effect.

THIRD AFFIRMATIVE DEFENSE

Schering's efforts to enforce its valid United States patent and prevent the sale of infringing goods, including all actions that are reasonably attendant to such efforts, such as reasonable settlements, are protected by the Patent Act, 35 U.S.C. § 271 et seq.

FOURTH AFFIRMATIVE DEFENSE

The complaint fails to allege that the procompetitive efficiencies of the settlements do not outweigh any actual or potential anticompetitive effects that could properly be ascribed to those agreements.

FIFTH AFFIRMATIVE DEFENSE

The relief sought by the complaint is contrary to public policy and not in the public interest in that it limits, interferes with and otherwise hampers the orderly maintenance, prosecution and settlement of patent infringement litigation, thereby raising the cost of patent enforcement, reducing the value of patents, and deterring innovation and dynamic efficiencies. It would also deter innovation on the part of generic manufacturers. Without a realistic opportunity of settlement, the prospect of lengthy and expensive infringement litigation will greatly discourage potential generic manufacturers from making the investments necessary to develop generic products. Such a result would be inconsistent with the purposes of the Hatch-Waxman Act and contrary to the strong public policy in favor of settlements generally.

SIXTH AFFIRMATIVE DEFENSE

The complaint and relief sought therein are barred in the ESI case under the doctrine of implied immunity because the court supervised and approved the settlement after having been apprised of all antitrust issues.

SEVENTH AFFIRMATIVE DEFENSE

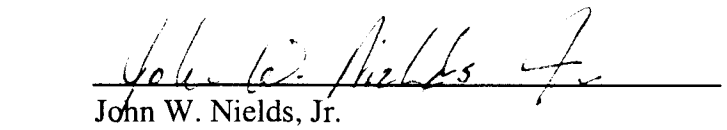
The settlement agreements between Schering and Upsher, and between Schering and ESI are immune from antitrust liability by virtue of the *Noerr-Pennington* doctrine.

Schering reserves the right to assert additional affirmative defenses as discovery proceeds.

PRAYER FOR RELIEF

WHEREFORE having fully answered the plaintiff's complaint, Schering denies that plaintiff is entitled to any relief whatsoever and respectfully requests judgment dismissing the complaint with prejudice and awarding to Schering the costs of the action, expert fees and reasonable attorney fees, as may be allowed by law, and such other relief as the Court deems just and appropriate.

Respectfully submitted,



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Attorneys for Respondent
Schering-Plough Corporation

Dated: April 23, 2001

CERTIFICATE OF SERVICE

I hereby certify that this 23rd day of April, 2001, the original and ten copies of the foregoing Answer of Respondent Schering-Plough Corporation were filed with the Secretary of the Commission, and that a copy was served by hand upon:

Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

and by regular United States mail, postage prepaid, upon each of the persons listed below:

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